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Bard Peripheral Vascular, Inc.*

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products
Liability Litigation,

No. 2:15-MD-02641-DGC

**THE PARTIES' JOINT STATUS
REPORT FOR THE FEBRUARY 17,
2017 CASE MANAGEMENT
CONFERENCE**

1 In accordance with Paragraph E of Case Management Order No. 19 [Doc. 4311],
 2 the Parties hereby submit their Joint Status Report for the February 17, 2017 Case
 3 Management Conference.

4 **I. Deposition Discovery**

5 **A. Fact Discovery**

6 The following depositions have been completed:

7	December 15, 2015	30(b)(6) re FDA Warning Letter
8	January 11, 2016	Kay Fuller
9	January 20, 2016	Continued 30(b)(6) re FDA Warning Letter
10	March 18, 2016	30(b)(6) re corporate structure
11	April 27, 2016	30(b)(6) re ESI systems structure
12	May 3, 2016	Murray Asch, M.D.
13	May 11, 2016	Carol Vierling
14	May 17, 2016	Anne Bynon
15	May 24, 2016	Len DeCant
16	June 2, 2016	John DeFord
17	June 9, 2016	Bret Baird
18	June 16, 2016	Robert DeLeon
19	June 17, 2016	Joe DeJohn
20	July 18, 2016	Abithal Raji-Kubba
21	July 27, 2016	Bill Little
22	July 27, 2016	Judy Ludwig
23	July 29, 2016	John Wheeler
24	August 9, 2016	Maureen Uebelacker
25	August 16, 2016	Daniel Orms
26	August 19, 2016	Mary Edwards
27	August 24, 2016	Cindi Walcott
28	August 30, 2016	30(b)(6) re REACH program

1	September 7, 2016	Steve Williamson
2	September 7, 2016	30(b)(6) re Sales/Marketing
3	September 7, 2016	Kevin Shifrin
4	September 16, 2016	Jack Sullivan
5	September 19, 2016	Brian Doherty
6	September 23, 2016	Holly Glass
7	September 29, 2016	John Van Vleet
8	October 11, 2016	Chris Ganser
9	October 18, 2016	Natalie Wong
10	November 3, 2016	Jack Sullivan (continued)
11	November 11, 2016	Robert Cortelezzi
12	December 6, 2016	David Peeler, M.D.
13	January 4, 2017	John Kaufman, M.D.
14	January 18, 2017	30(b)(6) Meridian/Denali
15	January 18, 2017	Kim Romney
16	January 19, 2017	30(b)(6) re Key Opinion Leaders
17	January 20, 2017	Scott Trerotola, M.D.
18	January 24, 2017	Scott Randall
19	January 26, 2017	30(b)(6) re Failure Rate Thresholds
20	January 26, 2017	Anthony Venbrux, M.D.
21	January 30, 2017	Frank Lynch, M.D.
22	January 31, 2017	Mark Wilson
23	February 1, 2017	William Stavropoulos, M.D.
24	February 2, 2017	Mike Randall
25	February 2, 2017	Kevin Boyle

The following depositions have been scheduled:

None at the time of this filing.

1 B. Barazza Discovery

2 The following depositions have been completed:

3 October 19, 2016	Diane Washington
4 October 28, 2016	James Holt
5 November 10, 2016	Gregory Lester
6 November 16, 2016	Maria Barazza
7 November 30, 2016	Edward Mims
8 December 1, 2016	Nancy Mosher
9 December 6, 2016	Thomas Flournay
10 December 6, 2016	Delmar Lee Peck
11 December 15, 2016	Denise Tomlin
12 January 24, 2017	John Van Vleet

13 The following depositions have been scheduled:

14 February 27, 2017	Linda Walker
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15 C. Discovery Group I

16 The following depositions have been completed:

17 January 25, 2017	Lisa Hyde
18 January 25, 2017	Mark Hyde
19 January 26, 2017	Justin Peterson
20 January 26, 2017	Lisa Peterson
21 January 26, 2017	Michael King
22 January 26, 2017	Jessica King
23 February 3, 2017	Doris Jones
24 February 3, 2017	Alfred Jones, Sr.
25 February 4, 2017	Joseph Mixson
26 February 4, 2017	Virginia Mixson
27 February 7, 2017	Deborah Ann Kaiser
28 February 7, 2017	Brandy Ball

February 8, 2017	Debra Mulkey
February 8, 2017	Joshua Thompson
February 8, 2017	Debra Ann Tinlin
February 8, 2017	James Tinlin

The following depositions have been scheduled:

February 13, 2017	Brent Dewitt
February 13, 2017	Providencia Dewitt
February 16, 2017	Randy Nelson
February 16, 2017	Judy Nelson
February 20, 2017	Sherr-Una Booker
February 20, 2017	Shomari Cottle
February 20, 2017	Carol Kruse
February 20, 2017	Diane Bierre

II. Anticipated Motion for Summary Judgment

A. Defendants' Position

Now that fact discovery has been completed, the defendants anticipate filing a motion for summary judgment applicable to all cases. Specifically, the defendants plan to file a motion for summary judgment demonstrating that plaintiffs' claims are impliedly and expressly preempted. Of course, the defendants are fully aware of the decision in Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), which generally held that claims involving medical devices cleared under the 510(k) process are not preempted.

The process utilized by the FDA to review Bard's inferior vena cava filters, however, is readily distinguishable from the process at issue in Lohr.¹

First, the statutory and regulatory framework of 510(k) review for medical devices has evolved significantly since the time the Lohr device was cleared for use. Perhaps

¹ As an aside, a number of courts have found tension between Lohr and later Supreme Court preemption decisions, and suggested that "perhaps some of those rules warrant revisiting and reconciliation." Caplinger v. Medtronic, Inc., 784 F.3d 1335, 1340 (10th Cir. 2015), cert. denied, 136 S. Ct. 796 (2016) (Gorsuch, J.).

1 more important, the extensive special controls the FDA imposed on Bard's filters, coupled
2 with the clinical studies required by the agency and the FDA's detailed review of the
3 devices demonstrate that the FDA imposed "requirements" for the devices that did not
4 exist in the Lohr scenario.

5 The plaintiffs' claim that expert discovery is needed before such a motion can be
6 adjudicated is incorrect. Courts throughout this country routinely decide preemption
7 motions at an early stage of the proceedings, either through Rule 12(b)(6) motions or
8 motions for summary judgment. That is because the preemptive effect of the regulatory
9 scheme and the FDA's activities requires a legal determination by the Court, and courts
10 generally do not look to experts retained by the parties to conduct that legal analysis. The
11 plaintiffs also claim that a recent evidentiary ruling by another court, involving another
12 product altogether, somehow precludes the filing of a good faith motion for summary
13 judgment in the first instance. There is no precedent for giving another court's evidentiary
14 ruling such a preclusive effect.

15 The motion contemplated by the defendants involves a critical issue, and one of
16 first impression concerning the particular product involved here. If permitted, the
17 defendants anticipate filing this motion by mid-March.

18 B. Plaintiffs' position

19 The Court previously addressed premature filings of summary judgment motions,
20 i.e., motions for "summary judgment must consider all relevant evidence collected and
21 presented by the parties." (*See*, Doc. 1481, Apr. 20, 2016.) Not all evidence has been
22 collected and presented by the parties at this juncture; neither party has yet engaged in
23 exchange of expert disclosures, exchanged reports, or otherwise conducted expert
24 discovery in this MDL. To allow for summary judgment motions on what Bard purports
25 to be significant changes in the "statutory and regulatory framework of 510(k) review for
26 medical devices" would be premature. That is because the claims Bard makes as a basis
27 for its request are squarely in the province of expert opinion including "extensive special
28 controls the FDA imposed on Bard's filters, coupled with the clinical studies required by

the agency and the FDA's detailed review of the devices". This is especially true since the parties are prohibited from conducting discovery on the FDA; Plaintiffs can neither cross examine nor otherwise conduct discovery against any employee of the FDA as to its actions, inactions, processes, etc. *See* 21 C.F.R. §20.1 (a-b). Thus, they would only be able to respond to Defendants' arguments regarding FDA processes through expert testimony – which has not yet taken place in this MDL.

Furthermore, the relevance of FDA evidence Bard seeks to use as a basis to preempt claims is tenuous at best. Bard is well aware of the holdings against it last year and again as to other defendants as recent as last month excluding FDA-related evidence as having no relevance to these types of cases. *See, Huskey v. Ethicon Inc., et al.*, Appeal 15-2118 (Doc. 55), United States Court of Appeals for the Fourth Circuit, January 26, 2017 (Appeal from the United States District Court for the Southern District of West Virginia, at Charleston. Joseph R. Goodwin, District Judge (2:12-cv-05201; 2:12-md-02327) (courtesy copy attached hereto as Exhibit A). *See also In re C.R. Bard, Inc., MDL No. 2187, Pelvic Repair Sys. Prods. Liab. Litig.*, 810 F.3d 913 (4th Cir. Jan. 14, 2016).

III. Plaintiffs' Request to Defer Expert Issues on Meridian and Denali Devices

A. Plaintiffs' position

Plaintiffs seek to continue deadlines for expert disclosures and discovery with regard to the Meridian and Denali devices only. Plaintiffs' basis for seeking this extension are as follows: First, none of the potential bellwether cases in Discovery Group 1 and in the early remand cases involve Meridian or Denali; all involve earlier devices (Recovery through Eclipse). Plaintiffs suggest that a later schedule for the Meridian and Denali expert disclosures and reports makes sense for when those cases will actually be tried and to focus the parties' current efforts and discovery on the cases that will be tried this year and next. Moreover, Plaintiffs have dealt with the late production consisting mostly of later generation devices, and still yet unresolved privilege log/redaction issues pending.

1 Defendants' argument regarding the amount of Meridian and Denali cases is
2 irrelevant to Plaintiffs' request. Plaintiffs do not ask to forego expert disclosure and
3 discovery on these devices forever; rather, Plaintiffs suggest that it is more practical to
4 focus immediate expert discovery on the cases that are going to be tried in the next 12 to
5 18 months and to come up with an expert disclosure schedule that makes sense for when
6 Meridian and Denali cases are actually likely to be tried.

7 Defendants' other arguments presuppose the contents of expert opinions and
8 reports relating to the later devices. While Bard's later devices are built on the foundation
9 of its Recovery and G2 devices, that does not necessarily mean that all the issues will be
10 the same. Indeed, Defendants typically claim quite to the contrary – attempting to
11 distance their later devices from their predicates. Certainly this Court is capable of
12 determining at a later time if rulings it makes as to expert opinions regarding earlier
13 devices should impact expert testimony regarding later devices.

14 Plaintiffs propose an extension as to the Meridian and Denali devices only.

15 B. Defendants' Position

16 The defendants object to the plaintiffs' attempt to effectively modify the
17 scheduling order and the structure of this MDL by delaying expert reports regarding the
18 Meridian and Denali filters. From its inception (more than a year ago), the schedule has
19 contemplated expert disclosures related to all cases, and now that the deadlines for those
20 disclosures are only weeks away, the parties' expert submissions addressing all filter
21 models should be nearing completion. To exempt the Denali and Meridian filters from
22 that requirement at this eleventh hour would unnecessarily prolong and complicate this
23 MDL.

24 It is true, as the plaintiffs note, that none of the 12 cases in Discovery Group I
25 happen to involve one of those two filters. However, together, those two filters make up
26 roughly 25% of the case inventory in this MDL (Meridian – 13%; Denali – 11%). In fact,
27 there are more cases involving both of those filters than there are involving the Recovery
28

1 Filter, which presently accounts for only 10% of the cases. Without question, those two
2 filters are a significant component of this proceeding.

3 To delay generic expert reports regarding those two filters would require the parties
4 (and the Court) to duplicate a great deal of their efforts. Second expert reports
5 (significantly overlapping the initial reports) would have to be submitted. Second
6 depositions would have to be taken of the experts when the time comes. Second Daubert
7 motions would have to be filed and considered, where appropriate. The need to duplicate
8 those multiple phases of the schedule would ultimately delay the remand and resolution of
9 the 25% of the cases involving those filters.

10 In short, the preparation of expert reports concerning those two later generation
11 filters should already be nearing completion. There is no basis for extending those
12 deadlines at this late juncture.

13 **IV. Further Deposition of Michael Randall**

14 Plaintiffs respectfully request that the Court order Defendants make available
15 Michael Randall for one half day of further deposition. Plaintiffs took the deposition of
16 Mr. Randall on February 2, 2017. After seven hours of testimony, Defendants terminated
17 the deposition based on the presumptive time limits of Rule 30(d)(1) and CMO 14.
18 Plaintiffs requested of Defendants at the time and request now of this Court that they be
19 permitted additional time to depose the witness based on Mr. Randall's failure to respond
20 directly and concisely to the majority of the questions posed to him. Defendants disagree
21 that additional time is necessary and oppose Plaintiffs' request.

22 **A. Plaintiffs' position**

23 Federal Rule of Civil Procedure 30(d)(1) provides that "[t]he court must allow
24 additional time consistent with Rule 26(b)(1) and (2) if needed to fairly examine the
25 deponent or if the deponent, another person, or any other circumstance impedes or delays
26 the examination." Here, Plaintiffs deposed Mr. Randall for seven hours in his individual
27 capacity. However, that time was not sufficient to fairly examine him as a result of his
28 repeated non-responsive and overlong answers to what were often very simple questions.

1 Mr. Randall is presently a Director in the research and development department at
2 Bard Peripheral Vascular. Mr. Randall began working on IVC filters at BPV in 2006; in
3 2008, he was the project leader for the “G2 Platinum” filter project; and by 2009, he was
4 project manager for all filters. In those capacities, he has been intimately involved in the
5 design, testing, and development of Bard’s IVC filters for the past nine years as well as
6 with responding to sales and quality assurance issues relating to them.

7 While his decade long involvement with filters alone supports an extended
8 deposition, Plaintiffs seek additional time because Mr. Randall’s manner of answering
9 questions unduly prolonged the deposition. Specifically, whether as a result of simply not
10 listening attentively, not understanding the questions, or for some other reasons, Mr.
11 Randall’s answers were unresponsive.

12 Simple yes-or-no questions often took multiple questions to elicit a proper,
13 responsive answer. Rather than burden the court with what would otherwise be a large
14 portion of the transcript, Plaintiffs have attached as Appendix A to this report examples of
15 Mr. Randall’s recurring failure to answer questions from approximately the first third of
16 the deposition transcript. These examples demonstrate that Mr. Randall repeatedly failed
17 to answer questions directly, requiring follow up questions – either repeating the question
18 that Mr. Randall had not answered or requiring counsel to engage in a series of questions
19 and answers that led back to Mr. Randall eventually answering the initial question.

20 The following question and answer is a succinct example of Mr. Randall’s failure
21 to answer simple questions with direct and responsive answers:

22 You do know that some filters move more frequently than other
23 filters. Correct?

24 MR. LERNER: Objection to form.

25 THE WITNESS: I know of -- what I know from the literature. There
26 are clinical studies out there that have migration -- that have migration rates
27 in them. I kind of -- I am hesitant to say I know how they react to one
28 another because to truly study and compare filters, they should be ran in a
prospective clinical study at the same time to ensure that they're being used
in the same manner, they have the same population. Then you can make a
comparison relative to each other to say, well, this one moves more than
this one.

1 Based upon the data that's out there, I know this company
2 manufacturer has a clinical trial that they've done, and it's a certain subset
3 of patient population, and the distribution is different than our clinical trial,
4 and they have a filter migration rate. We have a filter migration rate. So
5 there's different ones.

6 But to truly compare them, they should be run in the same clinical
7 study. They should have the same population, and they should be run under
8 the same guidance. I think that's the only way you can make a true
9 comparison of this filter migrates more than that filter.

10 In terms of do I know there's different rates out there by the
11 literature and different clinicals that they have, yes, I do know that because
12 every filter manufacturer has a clinical study conducted to commercialize
13 the device.

14 Transcript of deposition of Michael Randall at 61:11-62:16. The examples of this are
15 numerous and repeated throughout Mr. Randall's deposition and we have identified a
16 number of them in Appendix A from just the first third of the deposition.

17 In fairness to Mr. Randall, he did ultimately provide responsive answers in most
18 circumstances. However, his failure to answer simply and directly in the first instance
19 resulted in significantly lengthening his deposition – far too often he took long and
20 circuitous detours to get to those answers and it often took multiple questions to get
21 answers to relatively simple questions

22 At the second break in Mr. Randall's deposition, Plaintiffs' counsel raised these
23 issues with defense counsel, noting that if the witness continued to answer questions in the
24 way he had for the first two hours, the parties would not complete the deposition that day.
25 Plaintiffs' counsel asked defense counsel to speak with the witness to ask him to listen
26 more closely to the question and to answer those questions. Unfortunately, Mr. Randall's
27 manner of answering questions did not change. As a result, Plaintiffs were unable to
28 fairly complete the deposition of Mr. Randall.

29 In the meet and confer on this issue, Defendants did not suggest that Plaintiffs'
30 counsel's questioning or subject matters with Mr. Randall were in any way improper or
31 duplicative; however, they suggested generically that the examination of Mr. Randall in
32 his individual capacity was "overlapping" with his testimony as a Rule 30(b)(6) witness
33 for defendants on the Meridian and Denali filters. Defendants failed to provide any

1 express examples. Plaintiffs dispute this contention; the 30(b)(6) deposition addressed
2 general questions regarding the filters that were there subject, and in his role as corporate
3 representative, Mr. Randall gave testimony on behalf of the defendants on those subjects.
4 Not only is his personal testimony necessarily distinct from testimony given in the role as
5 a 30(b)(6) witness, Plaintiffs asked Mr. Randall entirely different questions on discrete
6 issues at his personal deposition than those asked when he testified on behalf of the
7 companies. The questions and testimony “overlap” only to the extent that both had to do
8 with the Meridian and Denali filters generally. Even then, only the last 150 minutes of the
9 seven hours of his personal deposition had anything to do with those filters. Simply,
10 Defendants’ contention lacks factual basis.

11 Plaintiffs believe they will need an additional three hours to complete their
12 intended deposition of Mr. Randall, particularly given that his manner of answering
13 questions requires more than what would be the normal amount of time for a witness. In
14 accordance with Rule 30(d)(1), Plaintiffs respectfully request the Court allow them that
15 additional time.

16 B. Defendants’ Position

17 The plaintiffs cannot justify their request to extend the deposition of Bard
18 employee Mike Randall. Mr. Randall is a Director of Research and Development at Bard
19 Peripheral Vascular. In that capacity, he has had supervisory responsibility for filters over
20 the last several years, including the development of the Meridian and Denali filters.

21 On January 18, 2017, Mr. Randall appeared as Bard’s corporate representative to
22 testify in response to a Fed. R. Civ. P. 30(b)(6) notice focused on the Meridian and Denali
23 filters. That deposition lasted an entire day, running from 9:00 a.m. until 5:20 p.m. Two
24 weeks later, on February 2nd, Mr. Randall was deposed in his individual capacity. That
25 deposition also focused heavily on the same filters (as evidenced by the fact that the word
26 “Denali” appears in the transcript 143 times, and “Meridian” appears 72 times). After
27 more than seven additional hours of testimony, the plaintiffs announced they needed at
28 least 2 more hours with the witness. Although Bard’s attorneys were willing to provide a

1 few additional minutes, they objected to prolonging the deposition as much as the
2 plaintiffs demanded.

3 Despite having deposed Mr. Randall for a total of 14 hours, the plaintiffs are now
4 demanding even more. They justify their request with the claim that Mr. Randall did not
5 respond to their questions, and somehow delayed the deposition. The transcript, however,
6 does not support their characterization. If anything, the transcript demonstrates that the
7 plaintiffs' counsel prolonged the deposition with combative and repetitive
8 questioning. The colloquies at Pages 57-65 and Pages 110-113 (attached collectively as
9 Appendix B) are just two examples.

10 Bard believes that, at some point, "enough is enough." Over a year of fact
11 discovery, the plaintiffs have taken dozens of depositions of Bard employees, including
12 six other employees involved with research and development. They have deposed Mr.
13 Randall twice, once as a corporate representative and once as an individual, for more than
14 14 hours. Bard objects to prolonging that deposition further.

15 **V. Production of Documents Relating to Employees Who May Have Been**
16 **Disciplined or Fired for Off Label Promotion**

17 Plaintiffs request the production of documents for six Bard employees who may
18 have been disciplined or fired for off label promotion. Bard has refused to supply this
19 information.

20 A. Plaintiffs' Position

21 In Plaintiffs Notice of 30(b)(6) (Opinion Leaders and Sales) Plaintiffs identified the
22 following topic:

23 10. Any employees of BARD who were disciplined in writing or fired for
24 promoting or selling the RELEVANT PRODUCTS in any situation that is contrary
25 to the IFUs. This should include, but not be limited to, the employee name,
26 position, year, supervisor and reason for such warning, discipline or firing.

27 In addition, Plaintiff requested the following documents in Request for Production
28 (RFP) 11:

11. Any documents regarding any employees of BARD who were disciplined in
writing or fired for promoting or selling the RELEVANT PRODUCTS in any
situation that is contrary to the IFUs. This should include, but not be limited to, the

1 employee name, position, year, supervisor and reason for such warning, discipline
2 or firing.

3 Bard initially refused to provide these documents and cited the following reason:

4 “As to sales reps who were terminated or were disciplined in writing for off-label
5 promotion of IVC filters, I have confirmed that Bard does not maintain a list of filter sales
6 reps who were terminated or disciplined in writing for off label promotion. The only way
7 to obtain that information would be for someone to go through the files of the hundreds of
8 sales reps that have been employed at Bard since 2002. So, given the tremendous burden
9 that would impose on Bard along with the Court’s previous order limiting the scope of
10 sales rep discovery in the MDL, we object to your request number 10.”

11 Plaintiffs have had numerous meet and confers with counsel for Bard over RFP
12 and further narrowed their request to the following Bard employees who were fired or
13 “left” Bard in 2008, including Jason Greer (who indisputably was fired for off label
14 promotion):

- 15 1. Jason Greer-District Manager of Sales
- 16 2. Robert DeLeon-Regional Manager of Sales
- 17 3. Janet Hudnall-Marketing Director
- 18 4. Bob Cortelezzi-Regional Manager of Sales
- 19 5. Joe DeJohn-Vice President of Sales
- 20 6. Jack Sullivan-Regional Manager of Sales

21 Despite this narrowed and targeted request for manager-level or higher employees,
22 defense counsel for Bard has still refused to supply this information.

23 It is undisputed in deposition testimony that more than 60 percent of Bard’s filters
24 are used off label. Jason Greer was specifically fired for off label promotion in 2008. At or
25 near that same time period, many of Bard's marketing and sales managers in charge of
26 IVC filters were either terminated or left Bard. This included: Robert DeLeon, Janet
27 Hudnall, Bob Cortelezzi, Joe DeJohn, and Jack Sullivan.
28

1 Through discovery thus far, Plaintiffs have uncovered an elaborate off label
2 marketing scheme starting with a plan written by marketing director Janet Hudnall to
3 expand uses of IVC beyond the indications for use. Numerous documents and testimony
4 support the execution of this plan.

5 In proving negligence and for punitive damages purposes, these documents will
6 further confirm this plan and Bard's knowledge of this scheme. At the very least,
7 Plaintiffs should be entitled to these requested documents at the managerial level.

8 B. Defendants' position

9 The plaintiffs originally requested that Bard identify and produce any documents
10 relating to "any" employee at Bard who was "disciplined in writing" or "fired" for off-
11 label promotion or sales of Bard's IVC filters for over a 14-year period. Given that Bard
12 does not maintain a list of such employees, Bard objected to the request because it would
13 have been incredibly burdensome and would have required a review of personnel files for
14 every employee who was engaged in marketing or sales of IVC filters spanning a period
15 of more than 14 years. As part of the meet and confer process, the plaintiffs then limited
16 (temporarily) that request to seven employees but also requested that Bard produce the
17 entire "employment files," notwithstanding the fact that by their very nature, employment
18 files contain highly sensitive and private information far beyond disciplinary and
19 termination information. The plaintiffs' request also listed employees who were not
20 terminated (John DeFord - who has now been removed from plaintiffs' list) and
21 employees who left the company well after 2008 (Jack Sullivan).

22 All of the listed employees have been deposed by current or former members of the
23 PSC, some on multiple occasions. There is no testimony or evidence from the millions of
24 pages of ESI and the over 100 corporate depositions that any of these individuals—with
25 the possible exception of Jason Greer, portions of whose employment file has been
26 previously provided—were disciplined or terminated for off-label promotion of Bard IVC
27 filters. Contrary to the plaintiffs' theory as to why there was a changing of the guard at
28 the sales managerial level, as has been explained in several corporate depositions, various

1 employees left BPV in or around 2008 after Bard hired a new BPV President. Not
 2 surprisingly, the new division president in turn began putting a new management team in
 3 place to oversee the dozens of products sold at the division, not because of any particular
 4 concern relating to Bard's IVC filters or the promotion of those filters.

5 While the plaintiffs have taken a few, out-of-context documents (primarily from
 6 the early 2000's) to try to support its off-label promotion claim, there is simply no
 7 evidence of any elaborate scheme by Bard to promote its filters off label. In fact, Bard
 8 has had extensive policies and procedures in place which prohibit off-label marketing or
 9 promotion of its products, including IVC filters.²

10 Notwithstanding the foregoing, Bard believes, as a compromise, that it would be
 11 appropriate to follow a similar approach that the Court took when the plaintiffs' requested
 12 the entire employment files for several Bard employees involved with the FDA Warning
 13 Letter. In that order, the Court provided that Bard "need not produce the entire
 14 employment files for these individuals [b]ut Defendants shall produce, under the
 15 protective order, documents from the files relating to any internal discipline, reprimands,
 16 adverse consequences, negative employment reviews, or comparable information, taken
 17 against any of these four individuals on the basis of under-reporting or non-reporting
 18 addressed in the FDA warning letter." CMO 13 (June 21, 2016). Similarly, Bard
 19 respectfully requests that the Court limit the production of employment files for the listed
 20 employees to only those non-privileged portions relating to those employees being
 21 disciplined or terminated (if any) for off-label promotion of Bard's IVC filters.

22 **VI. Other Issues Not Yet Ripe for the Court**

23 The parties are currently engaged in attempts to meet and confer regarding several
 24 issues with respect to Defendants' production of documents, privilege issues, and
 25

26 ² Of note, the medical community accepts and recognizes the benefits of IVC filters for
 27 various uses and has set guidelines for their use even when technically being used "off-
 28 label." See., e.g., Caplin, Drew, *Quality Improvement Guidelines for the Performance of*
Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism, VASC
 INTERV RADIOL 2011; 22:1499, 1501 (2011). Even the Bard FDA-approved clinical studies
 and protocols for filters have included off-label uses.

1 responses to written discovery. At this time, those issues may still be resolved and are not
 2 ripe for determination by the Court. These include the following:

- 3 1. The stripping and non-production of certain attachments to emails produced
 4 by Defendants;
- 5 2. Issues with respect to Defendants' redaction of produced materials;
- 6 3. Defendants' privilege log for the documents produced beginning in
 7 September 2016;
- 8 4. Defendants' responses and objections to Plaintiffs' first set of
 9 interrogatories; and
- 10 5. Defendants' responses and objections to Plaintiffs' second set of
 11 interrogatories.

12 The defendants note that many of these issues were not raised by the plaintiffs until
 13 February 8th. The defendants are working with the plaintiffs' counsel, and anticipate that
 14 the issues should be resolved without the need of the Court's intervention.

15 **VII. Future Joint Submissions**

16 To ameliorate logistical issues that have arisen repeatedly with the preparation of
 17 these joint submissions, the defendants ask that future orders require the parties to
 18 exchange drafts of the submission containing any issues they want addressed at least four
 19 (4) business days before the filing deadline, and that the parties exchange responses to
 20 each side's proposed submissions two (2) days before the deadline.

21 Respectfully submitted this 13th day of February 2017.

22 GALLAGHER & KENNEDY, P.A.

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8 **CERTIFICATE OF SERVICE**

9 I hereby certify that on February 13, 2017, the foregoing was electronically filed
10 with the Clerk of Court using the CM/ECF system which will automatically send email
11 notification of such filing to all attorneys of record.

12 s/ Deborah Yanazzo
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